

REMARKS/ARGUMENTS

This amendment is in response to the final official action mailed on April 3, 2008. Entry of the foregoing and favorable reconsideration and reexamination of the subject application pursuant to and consistent with 37 C.F.R. Section 1.112, and in light of the remarks which follow, are respectfully requested.

Claims 61 and 88 have been amended, claim 63 has been cancelled, claims 90-92 are new, and claims 62, 70-72, 76, 77, 82, 84, 85 and are pending. The claim amendments are purported by original claim 63. Support for new claim 90 is found at pages 22-25. Support for new claims 91 and 92 is found at claims 61 and 88 and at page 1, lines 35-38; page 2, lines 1-10; and page 23, lines 24-28. No new matter has been added.

Rejection of Moy in view of Milkova and Alonso and Moy and Werman in view of Milkova and Alonso

The Examiner has rejected claims 61, 63, 71, 72, 76, 77, 82, 84, and 85 under 35 U.S.C. § 103(a) as allegedly unpatentable over Moy (U.S. 5,928,659) in view of Milkova ("Study on the Chemical Nature of Sterols Contained in Bulgarian Sunflower Oil") and Alonso ("Determination of Mixtures in Vegetable Oils and Milk Fat by Analysis of Sterol Fractions by GC"). The Examiner contends that Moy teaches all of the elements of the claimed invention except for administering at least one plant oil selected from oil distillate of sunflower oil or unsaponifiable materials from sunflowers (hereinafter "material from sunflowers"). The Examiner believes that it would have been obvious for one skilled in the art to add the oils or unsaponified materials from sunflowers to Moy or, alternatively, to replace the avocado oils of Moy with oils or unsaponified materials from sunflowers as in the claimed method of treating skin. The Examiner states that this addition or

substitution would have been obvious "because at the time [of] the invention, *Milkova* taught that the major sterol fractions of crude sunflower oil...are sitosterol, campesterol, and stigmasterol." The Examiner also states that *Alonso* "taught that unsaponifiable materials from sunflower oil comprise sitosterol, campesterol, and stigmasterol." *Office Action*, page 4.

For largely the same reasons as recited above, the Examiner has rejected claims 61, 63, 71-72, 76, 82, 88, and 89 under 35 U.S.C. § 103(a) as allegedly unpatentable over *Moy* and *Werman* (Connect Tissue Res, 1991; 26(1-2): 1-10) in view of *Milkova* and *Alonso*. Applicants traverse each of these rejections, which will be addressed together.

First, Applicants have amended claims 61 and 88 to include the limitation that the quantity of at least one skin lipid selected from the group consisting of cholesterol, cholesterol sulfate, ceramide 1, and ceramide 2 is increased through administration of the claimed composition. *Moy* is directed to methods of treating skin by topically applying a composition comprising unsaponifiable lipids from avocado fruit or seed (hereinafter "materials from avocados"). Unlike the claimed invention, *Moy* provides no disclosure that skin lipid concentration increases after administration of materials from avocados. Instead, *Moy* merely states that the combination of avocado oil "in a bland dermatologically acceptable vehicle show[s] a dramatic ability to ameliorate skin blemishes..." Col.4, ll.15-20.

Nor do *Milkova* or *Alonso*, which are merely directed to the isolation and structural elucidation of sunflower based materials, disclose that administration of an oil or unsaponifiable material, regardless of source, increases skin lipid concentration. Specifically, *Milkova* is directed only to the isolation of certain sterols by preparative TLC. Similarly,

Alonso "deals with the application of a GC procedure for rapid analysis of the total sterol fraction of vegetable oils, milk fat, or mixtures, to detect any admixture of sunflower or olive oil and any addition of vegetable oils to milk fat." *Alonso*, page 1. Clearly these references do not contemplate the biological properties of sterols, and certainly they do not teach increasing the concentration of at least one of cholesterol, cholesterol sulfate, ceramide 1, or ceramide 2 through administration of a sterol. Therefore, the claims as amended, and new claims 91 and 92, cannot be obvious over the cited references.

Similarly, *Werman* does not disclose increasing skin lipid concentrations. In fact, *Werman* provides that "total collagen content [is] not affected." *Werman*, abstract. Moreover, collagen is not even a skin lipid but rather a protein. Accordingly, *Werman* does not teach increasing the concentration of skin lipids, and certainly not increasing cholesterol, cholesterol sulfate, or ceramides as in claims 61, 88, 91, and 92. Therefore, the rejections must be withdrawn.

Second, and contrary to the Examiner's assertions, Applicants submit that one skilled in the art would not have been motivated to substitute materials from avocado with materials from sunflowers with any reasonable expectation of success in treating skin conditions. There is no disclosure or suggestion in *Moy* that material from sunflowers can be substituted for material from avocados. In fact, *Moy* provides no disclosure of adding or substituting any other types of oils or unsaponifiable lipids regardless of source.

Moreover, *Moy* provides no evidence, and certainly no disclosure, of which single material, or combination of materials, from avocado provides for the results observed. *Moy* simply states that "the unsaponifiabiles [from avocado oil]

contain some active ingredient beyond stigmasterol."¹ Moy, Col. 4, 11.5-7. While Moy indicates that stigmasterol, sitosterol, and campesterol are contained in avocados, in addition to other organics including alkanes, long chain alcohols, and other sterols, it provides no disclosure of which of these, if any, provides the beneficial results. It cannot be assumed, therefore, that because sunflower oils and unsaponifiable materials from sunflowers contain some compounds in common with avocados, that simply substituting sunflowers for avocados will provide the same results. Nor could it be assumed that the same or similar quantities of the unidentified result-producing material(s) are present in sunflower oils, avocado oils, or soy oils. There is simply no basis for one skilled in the art at the time of filing to make these assumptions based on the art or record.

Further, neither *Milkova* or *Alonso* supply what is missing, i.e. an indication of which sunflower-based material(s) provide the observed beneficial results. There is no disclosure in either of these references that any of the materials can be used to treat or cure skin conditions or that the materials increase skin lipid concentrations. Nor is there any disclosure in either of these references that materials from sunflowers can be used as a substitute for the materials from avocados or that similar materials are present in both sunflowers and avocados.

¹ Even *Robert* (Pharmacology of Connective Tissue, Effect of Avocado and Soybean Unsaponifiables on Metabolism of the Intracellular Matrix), cited in Moy and in the Official Action dated 4/7/2007, provides that neither cortisone nor stigmasterol produce the same effect as the effect produced by unsaponifiables, i.e. diminishing the effect of collagen and increasing the amount of tissue lipids. See *Robert*, translation at page 3, last paragraph, page 7, first paragraph. *Robert* then shows that avocado-soybean unsaponifiables on the one hand and stigmasterol on the other hand, produce distinct effects, and that "still unknown ingredients exist in these unsaponifiables that possess important activity on the composition and metabolism of connective tissue. *Robert*, page 7, third paragraph; page 8, second paragraph. Accordingly, there is no indication in the cited references or *Robert* that unsaponifiable materials from sunflowers contain

Accordingly, one skilled in the art at the time of the invention would not have been motivated by the secondary references to add materials from sunflowers to the compositions of *Moy* or to substitute materials from sunflowers for those in *Moy* to arrive at the claimed invention. Therefore, the rejections must be withdrawn.

Rejection of *Seipel* in view of *Ghosh*, *Milkova* and *Alonso*

The Examiner has also rejected claims 61, 63, 71-72, 76, 77, 82, 84 and 85 under 35 U.S.C. § 103(a) as allegedly unpatentable over *Seipel* et al. WO 99/18913 in view of *Ghosh* et al. ("Isolation of Tocopherol and Sterol Concentrate from Sunflower Oil Deodorizer Distillate"), *Milkova* et al. and *Alonso* et al.. The Examiner states that *Seipel* "teaches that the reference sterol esters are useful in increasing skin lipids and restoring natural oils to affected skin." *Office Action*, page 6, emphasis added. Moreover, the Examiner contends that while *Seipel* "does not teach a method of topically administering [a] sterol ester-containing composition[] to provide a method of treating skin conditions" it would have been obvious, in view of the secondary references, that the compositions of *Seipel* could have been used to treat skin.

First, and in contrast to the statements made by the Patent Office, *Seipel* does not teach increasing skin lipid concentrations as in amended claims 61 and 88 and new claims 91 and 92. Instead, *Seipel* is directed only to the use of sterol esters as agents for restoring natural oils for the production of skin and hair care products. *Seipel*, translation page 1 (abstract, description), page 8 (examples). Nor do any of the secondary references disclose administering sterol esters to increase skin lipid concentrations. Certainly there is no

the same qualitative and quantitative composition as materials from avocados or soybeans.

disclosure in any of the cited references that concentrations of any of cholesterol, cholesterol sulfate, ceramide 1, or ceramide 2 are increased. Accordingly, the rejection as applied to the new and amended claims must be withdrawn.

Second, *Seipel* teaches that the sterol esters are derived from "palm oil, coconut oil, or soybean oil." *Seipel*, translation page 1. Similar to the arguments provided in the above rejections, there is no disclosure in *Seipel*, or any of the secondary references, that materials from sunflowers, or for that matter any other source, can be substituted. Nor is there any indication in *Seipel* or the secondary references of which single material, or combination of materials, from palm oil, coconut oil, or soybean oil provide the restoring properties observed. Even if some materials are commonly found in both sunflowers and other sources, there is no indication to those skilled in the art that simply substituting one source for another would provide the same results. Indeed, without further qualitative and/or quantitative analysis of the different materials in each source, and the properties they each impart, one skilled in the art would not find it obvious to substitute, or add, materials from sunflowers to arrive at the claimed invention. Therefore, the rejections should be withdrawn.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he/she telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with

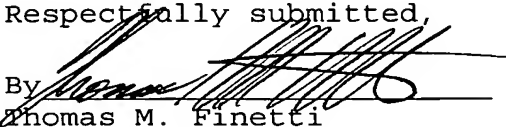
Application No.: 10/088,851

Docket No.: REGIM 3.3-012

this requested amendment, the Examiner is authorized to charge
Deposit Account No. 12-1095 therefor.

Dated: August 1, 2008

Respectfully submitted,

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